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| 09/503,089      | 02/11/2000  | Amanda J. Patel      | 1030-R-00           | 6089             |

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EXAMINER

CANELLA, KAREN A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

DATE MAILED: 05/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/503,089

Applicant(s)

Patel et al

Examiner

Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-20, 22, 23, and 25 is/are pending in the application.
- 4a) Of the above, claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-16, 18-20, 22, 23, and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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***Response to Amendment***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 13, 18, 19, 20, 22, 23 have been amended. Claims 17, 21 and 24 have been canceled. Claims 1-12 remain withdrawn from consideration. Claims 13-16, 18-20, 22, 23 and 25 are under consideration.

***Claim Rejections Withdrawn***

3. The rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn..
4. The rejection of claims 14-16, 18, 22 and 25 under 35 U.S.C. 112, first paragraph, is withdrawn in light of applicants amendment to the claims deleting the word "safe".
5. The objection to claims 19, 20 and 23 under 37 CFR 1.75(c) is withdrawn in light of applicants amendments to the claims.

***Claim Rejections Maintained***

6. The rejection of claims 13, 19, 20 and 23 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record. The instant claims are drawn to method of identifying substances having anesthetic properties comprising contact a test substance with transfected cells expressing proteins having 95% sequence identity to TREK or TASK, wherein the observation of outward-going potassium rectification in said cells is indicative that the test substance has anesthetic properties. The prior rejection has set forth the references of Burgess et al and Lazar et al to demonstrate the unpredictable nature of altering protein amino acid sequence with regard to protein function. The previous rejection also sets forth the reference of Fink et al (EMBO,

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1996, Vol. 15, pp. 1247-1252) to demonstrate the lack of correlation between protein sequence similarity with TREK and the ability of a similar protein to function as an outwardly-rectifying potassium channel. Applicant argues that it is well known in the art (Lehninger, biochemistry text) that conservative amino acid substitutions may be made that do not affect the function of the protein and that one of ordinary skill in the art knows that replacement of an amino acid residue in a polypeptide by another residue with similar properties is not likely to alter the function of the protein. Applicant further argues that page 7 of the specification explains that substantial identity is understood to mean that the protein remains active as a potassium transport protein, and that the specification teaches that substitutions can be made without significantly affecting the function of the protein. This has been considered but not found persuasive. The specification contemplates variants of TREK and TASK that retain their functional activity, but the specification does not specifically teach how to make said variants. The specification fails to limit the amino acid substitutions to conservative amino acid substitutions, and the specification fails to teach which amino acid residues are tolerant of substitution.

Applicant further argues that the teachings of Fink et al regarding the lack of correlation between structural similarity and function with respect to TREK and TWIK do not apply as the claims are drawn to 95% sequence identity with the primary structure of TREK or TASK. The examiner maintains that this illustrates the unreliability of the art with respect to anticipating the function of a protein from the primary amino acid sequence, as structural similarity is based upon conserved motifs present in the primary amino acid sequence.

7. The rejection of claims 13, 15, 16, 18, and 20 under 35 U.S.C. 103(a) as being unpatentable over Franks and Lieb (Nature, 1994, Vol. 367, pp. 607-614) in view of Fink (EMBO, 1996, Vol. 15, pp. 6854-6862), is maintained for reasons of record.

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8. The rejection of claims 13, 14, 22 and 25 under 35 U.S.C. 103(a) as being unpatentable over Franks and Lieb (Nature, 1994, Vol. 367, pp. 607-614) in view of Duprat et al (EMBO, 1997, Vol. 16, pp. 5464-5471), is maintained for reasons of record.

9. Applicant argues that there is no motivation to combine Franks and Lieb with Fink or Duprat et al as there are no teaching indicating that the potassium channels of TREK-1 or TASK are the same as the  $I_{K(an)}$  potassium channel of anesthetic-sensitive molluscan neurons. This has been carefully considered but not found persuasive.

The biophysical properties of the potassium channel disclosed by Fink et al appear to be the same as the  $I_{K(an)}$  channel of sensitive molluscan neurons. For instance, both channels are fast, transient, outward rectifying potassium channels, which are inhibited in low-sodium solutions (compare Frank and Lieb, Nature, 1988, vol. 333, pp. 664, at page 662, second column, lines 32-36 with Fink et al, 1996, page 6857, first column, lines 17-21 and page 6857, second column, lines 12-15), are sensitive to external potassium concentrations (compare Frank and Lieb, page 662, lines 42-47 with Fink et al, page 6858, column 1, lines 4-16) and are non-voltage gated (compare Frank and Lieb, page 662, second column, line 58 to page 663, first column, line 4 with Fink et al, page 6858, figure 4). Therefore, one of skill in the art would recognize that the potassium channel of TREK was a mammalian equivalent of the molluscan  $I_{K(an)}$  channel which is known in the art to respond to anesthetics that correlates with clinical response to anesthetics in mammals. Thus there is a motivation to combine the references of Franks and Lieb (Nature, 1994, Vol. 367, pp. 607-614) and Fink (EMBO, 1996, Vol. 15, pp. 6854-6862) to render obvious method of identifying substances having anesthetic properties.

Duprat et al teach that TASK has biophysical properties that resemble the molluscan S channels (page 5469, column 1, lines 5-13) which is the same as the  $I_{K(an)}$  channel. Thus there is a motivation to combine the references of Franks and Lieb (Nature, 1994, Vol. 367, pp. 607-614) and Duprat et al (Duprat et al (EMBO, 1997, Vol. 16, pp. 5464-5471) to render obvious method of identifying substances having anesthetic properties.

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***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.  
Patent Examiner, Group 1642  
May 6, 2002

  
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